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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,566	08/21/2006	Noboru Yamazaki	Q92967	6156
23373 7590 07/06/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER KISHORE, GOLLAMUDI S	
			ART UNIT 1612	PAPER NUMBER
			NOTIFICATION DATE 07/06/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/566,566	Applicant(s) YAMAZAKI ET AL.	
	Examiner GOLLAMUDI S. KISHORE	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) 5-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 5-15, 27-41 and 65-71 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8-21-06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-15, 27-41 and 65-71 in the reply filed on 4-23-10 is acknowledged.

2. Claims 5-15, 27-41 and 65-71 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim 5, 7, 10, 15, 27, 29-34, 36-37, 65 and 67-71 are not been further treated on the merits.

Claims included in the prosecution are 1-4.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First of all, it is unclear whether the limitations recited in parenthesis are indeed the limitations in claim 1. Secondly, it is unclear as to what applicant intends to convey by "not less than one lipid". This terminology is confusing since in parenthesis applicant indicate the lower limit of 0 percentage). Also confusing is the 0 % lower limit for phosphatidylcholine and phosphatidylethanolamine which for the liposomes. If they are 0 how can one form liposomes?

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It is unclear as to what applicant intends to convey by “at least one lipid ----- gathers on the surface of the liposome to form a raft”. Liposomes are bilayer structures and any lipid will be within the bilayer. If so, what is meant by a raft?

It is unclear what applicant intends to convey by “sugar chain controlled in type and density is bonded” in claim 4. Furthermore, the term, “type” is an indefinite term.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Redzeniak (5,686,103).

Redzeniak discloses liposomal formulations wherein the liposomal surface is covered with sugar residues. The sugars are attached to the surface by a linker molecule, which is BSA. The liposomes encapsulate a drug. The liposomes contain phosphatidylcholine, dicetyl phosphate and cholesterol (abstract, Figures, Examples and claims).

7. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Lau (5,567,432).

Lau discloses liposomes containing distearoyl lecithin, dicetylphosphate, cholesterol and sugar residues attached to the vesicle membrane (abstract, Figure 1 A, Figure 3, Figure 6 B, Examples and claims).

7. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakabayashi (5,243,035).

Nakabayashi discloses liposomal formulations wherein the liposomal surface is covered with sugar residues (sialic acid). The sugars are attached to the surface by a spacer arm. The liposomes encapsulate a drug. The liposomes contain phosphatidylcholine, cholesterol (Abstract, Examples and claims).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staveski (5,354,853) by itself or in combination with Redzeniak or Lau cited above.

Staveski discloses liposomal formulations wherein the liposomal surface is covered with sugar residues (lactose). The sugars are attached to the surface by a spacer arm (alkyl). The liposomes encapsulate a drug (col. 3, line 43 through col. 4, line 34, Examples and claims). Staveski however, do not specifically teach the lipids which make the bilayer structure of the liposomes. However, since it is well known in the art that phospholipids such as phosphatidylcholine, phosphatidylglycerol, phosphatidylethanolamine and cholesterol are art known liposomal components, it would have been obvious to one of ordinary skill in the art to use these liposomal lipids

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along with the sugar derivatives of Staveski with a reasonable expectation of success. One of ordinary skill in the art would be motivated to use the phospholipids, cholesterol and dicetylphosphate in the liposomes of Staveski since Redzeniak and Lau teach the use of these components in liposomes containing sugar residues.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GOLLAMUDI S. KISHORE whose telephone number is (571)272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

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